IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GALDERMA LABORATORIES, L.P. and NESTLÉ SKIN HEALTH S.A.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
SUN PHARMACEUTICAL INDUSTRIES LIMITED and SUN PHARMACEUTICAL INDUSTRIES, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Galderma Laboratories, L.P. ("Galderma") and Nestlé Skin Health S.A. ("NSH") (collectively, "Plaintiffs"), for their Complaint against Defendants Sun Pharmaceutical Industries Limited ("Sun Ltd.") and Sun Pharmaceutical Industries, Inc. ("Sun Inc.") (collectively, "Sun" or "Defendants"), hereby allege as follows:

THE PARTIES

1. Plaintiff Galderma is a privately held partnership registered in the State of Texas, having a principal place of business at 14501 North Freeway, Fort Worth, Texas 76177.

2. Plaintiff NSH is a "société anonyme" organized and existing under the laws of Switzerland, having a principal place of business at Avenue Gratta Paille 2, 1018 Lausanne, Switzerland.

3. Upon information and belief, Defendant Sun Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai, Maharashtra, India 400063.

4. Upon information and belief, Defendant Sun Inc. is a corporation organized and existing under the law of the State of Michigan, having a principal place of business at 270 Prospect Plains Road, Cranbury, New Jersey 08512.

5. Plaintiffs Galderma and NSH, and Defendants Sun Ltd. and Sun Inc. are presently parties to a related action pending in this district, *Galderma Laboratories, L.P., et al. v. Sun Pharm. Indus. Ltd., et al.*, C.A. No. 16-1003-LPS (D. Del.) ("the *Sun I* Action"). The *Sun I* Action concerns, among other things, Plaintiffs' assertion that Sun has infringed United States Patent Nos. 7,211,267 ("the Ashley '267 patent"); 7,232,572 ("the Ashley '572 patent"); 8,603,506 ("the Ashley '506 patent"); and 9,241,946 ("the Ashley '946 patent") (collectively, "the Related Ashley patents") through Sun's submission to the U.S. Food and Drug Administration ("FDA") and maintenance of New Drug Application ("NDA") No. 209259 ("Sun's NDA") for a 40 mg doxycycline tablet product ("Sun's NDA Product"), for which Sun seeks approval prior to the expiration of the Related Patents. *See generally* D.I. 1, C.A. No. 16-1003-LPS.

6. As set forth below, Plaintiffs now bring the instant action regarding Sun's infringement of United States Patent No. 10,058,564 ("the Ashley '564 patent") (Exhibit A), arising from the same infringing acts by Sun as asserted in the *Sun I* Action presently pending before this Court.

NATURE OF THE ACTION

7. This is a civil action for infringement of the Ashley '564 patent. This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 et seq., as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

10. This Court has personal jurisdiction over Defendants Sun Ltd. and Sun Inc. by virtue of the fact that, *inter alia*, Defendants have committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led or will lead to foreseeable harm and injury to Plaintiffs, including in the State of Delaware. Upon information and belief, Defendants intend to engage in the commercial manufacture, use, and/or sale under Sun's NDA of Sun's NDA Product, before the expiration of the Ashley '564 patent, throughout the United States, including in the State of Delaware.

11. Upon information and belief, Sun Ltd. is in the business of, *inter alia*, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the State of Delaware, through its own actions, and through the actions of its agents and affiliates, including, at least, Sun. Inc.

12. Upon information and belief, Sun Inc. is in the business of, *inter alia*, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the State of Delaware, through its own actions, and through the actions of its agents and affiliates, including, at least, Sun Ltd. Upon information and belief, Sun Inc. is a wholly owned subsidiary of Sun Ltd.

13. Upon information and belief, Sun Inc. has a designated agent in Delaware, The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801. Upon information and belief, Sun Inc. holds a Pharmacy Wholesale License from the State of Delaware under License No. A4-0002148. Upon information and belief, Sun Inc. holds a Distributor/Manufacturer License for Controlled Substances from the State of Delaware under License No. DM-0010549.

14. Upon information and belief, Sun Ltd. and Sun Inc. have participated and collaborated in the preparation, filing and seeking FDA approval of NDA No. 209259 for Sun's NDA Product; continue to participate and collaborate in seeking FDA approval of NDA No. 209259; and intend to participate and collaborate in the commercial manufacture, marketing offer for sale, and sale of Sun's NDA Product throughout the United States including the State of Delaware.

15. Sun's infringing activities with respect to its filing of NDA No. 209259 and intent to commercialize Sun's NDA Product have led and/or will lead to foreseeable harm and injury to Plaintiffs, including in Delaware.

16. This Court also has personal jurisdiction over Sun Ltd. and Sun Inc. by virtue of the fact that, upon information and belief, *inter alia*, Sun Ltd. and Sun Inc. have availed themselves of the rights and benefits of Delaware law, and have engaged in systematic and continuous contacts with the State of Delaware.

17. This Court also has personal jurisdiction over Defendants Sun Ltd. and Sun Inc. because they have previously submitted to the jurisdiction of this Court and have further previously availed themselves of this Court by initiating lawsuits, consenting to this Court's jurisdiction and asserting counterclaims in other civil actions initiated in this jurisdiction, including in the related *Sun I* Action pending before this Court. *See Galderma Laboratories, L.P., et al. v. Sun Pharm. Indus. Ltd., et al.*, No. 16-1003-LPS (D. Del.); *see also Sun Pharm. Indus. Ltd. v. Wyeth*, No. 09-0083-SLR (D. Del.) (Complaint filed by Sun Pharmaceutical Industries Ltd.); *AstraZeneca AB v. Sun Pharma Global FZE et al.*, No. 14-cv-0694-GMS (D. Del.) (D.I. 12) (Sun Pharmaceutical Industries Ltd. submitted counterclaims and did not contest jurisdiction); *Sanofi et al. v. Sun Pharma Global FZE et al.*, No. 14-0294-RGA (D. Del.) (D.I.

19) (same); *Pfizer Inc. et al. v. Sun Pharma Global Inc. et al*., No. 09-0313-GMS (D. Del.) (D.I. 13) (Sun Pharmaceutical Industries, Ltd. and Sun Pharmaceutical Industries, Inc. submitted counterclaims and did not contest jurisdiction); *Acorda Therapeutics, Inc. v. Sun Pharma Indus. Ltd., et al.*, No. 1:15-cv-0391-LPS (D. Del.) (D.I. 8) (same); *Millennium Pharma, Inc. v. Sun Pharma Indus. Ltd., et al.*, No. 15-0540-GMS (D. Del.) (D.I. 12) (Sun Pharmaceutical Industries, Ltd. submitted counterclaims and did not contest jurisdiction); *Sanofi et al. v. Sun Pharma Global FZE et al.*, No. 15-1208-RGA (D. Del.) (D.I. 11) (same).

THE ASHLEY '564 PATENT

18. Plaintiff Galderma holds New Drug Application ("NDA") No. 50-805 on ORACEA® (doxycycline, USP) 40 mg Capsules, and is the exclusive distributor of ORACEA® Capsules in the United States.

19. On August 28, 2018, the Ashley '564 patent, entitled "Methods of Treating Acne" was duly and legally issued to Galderma. The Ashley '564 patent is from the same patent family as the Related Ashley patents, which also name Robert A. Ashley as the inventor.

20. NSH is the current owner of the Ashley '564 patent.

21. The Ashley '564 patent is listed in the *FDA's Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for ORACEA® Capsules.

SUN'S NDA AND NOTICE LETTER, AND THE *SUN I* ACTION

22. Upon information and belief, Sun Ltd., with the collaboration or assistance of Sun Inc., submitted NDA No. 209259 to the FDA under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(b)(2)), including a certification under § 505(b)(2)(A)(iv) of the Federal Food, Drug and Cosmetic Act ("Paragraph IV Certification"), seeking approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of Sun's NDA Product prior to the expiration of the patents

listed in the Orange Book for ORACEA® Capsules, which at that time included, among other things, the Related Ashley patents

23. Sun Ltd. sent a letter to Plaintiffs dated September 14, 2016, representing that Sun Ltd. had filed a Paragraph IV Certification in NDA No. 209259 with respect to the Related Ashley patents and other Orange Book listed patents for ORACEA® Capsules, and that Sun is seeking approval of its NDA Product under NDA No. 209259 prior to the expiration of those patents ("the Sun Notice Letter").

24. Plaintiffs commenced the *Sun I* Action against Sun with a Complaint filed in this Court on October 27, 2016. *See* D.I. 1, C.A. No. 16-1003-LPS. Sun filed its Answer and Counterclaims in the *Sun I* Action on November 21, 2016 (D.I. 11, C.A. No. 16-1003-LPS), and Plaintiffs filed their Answer to Sun's Counterclaims in the *Sun I* Action on January 9, 2017 (D.I. 19, C.A. No. 16-1003-LPS). As of the date of this Complaint, the *Sun I* Action is presently in expert discovery, with trial scheduled for December 10-14, 2018.

25. The Ashley '564 patent was listed in the Orange Book for ORACEA® Capsules on September 25, 2018. Upon information and belief, Sun continues to seek approval of its NDA Product prior to the expiration of the Orange Book listed patents for ORACEA® Capsules, despite the new issuance and listing of the Ashley '564 patent.

SUN'S INFRINGEMENT OF THE PATENT-IN-SUIT

26. Plaintiffs re-allege paragraphs 1-25 as if fully set forth herein.

27. By seeking approval of NDA No. 209259 to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of Sun's NDA Product prior to the expiration of the Ashley '564 patent, Sun has infringed that patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

28. Defendants Sun Ltd. and Sun Inc. are jointly and severally liable for infringement of the Ashley '564 patent under 35 U.S.C. § 271(e)(2)(A). Upon information and belief, Sun Ltd. and Sun Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, or directed the submission of NDA No. 209259 seeking to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of Sun's NDA Product prior to the expiration of the Ashley '564 patent.

29. Moreover, if Sun manufactures, uses, offers for sale, or imports into the United States any of Sun's NDA Product, or induces or contributes to any such conduct, prior to the expiration of the Ashley '564 patent, including any applicable exclusivities or extensions, Sun would infringe one or more claims of the Ashley '564 patent under 35 U.S.C. § 271(a), (b) and/or (c), either literally or under the doctrine of equivalents.

30. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of NDA No. 209259 be a date that is not earlier than the expiration date of the Ashley '564 patent, or any later expiration of any patent term extension or exclusivity for the Ashley '564 patent to which Plaintiffs become entitled.

31. Plaintiffs will be irreparably harmed by Sun's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

Plaintiffs request that the Court grant the following relief:

A. An Order adjudging and decreeing that Defendants Sun Ltd. and Sun Inc. have infringed the Ashley '564 patent by submitting NDA No. 209259 to the FDA;

B. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Sun's NDA No. 209259 will not be earlier than the expiration date of the

Ashley '564 patent, or any later expiration of any patent term extension or exclusivity for the aforementioned Ashley '564 patent to which Plaintiffs are or become entitled;

C. An Order permanently enjoining Defendants Sun Ltd. and Sun Inc., their directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, from manufacturing, using, offering to sell, selling, marketing, distributing, or importing Sun's NDA Product identified in this Complaint, or any product that infringes the Ashley '564 patent, prior to the expiration of the Ashley '564 patent, including any extensions to which Plaintiffs are or become entitled;

D. That Plaintiffs be awarded monetary relief to the extent Defendants commercially manufacture, use, offers for sale, or sell within the United States, or import into the United States any product that infringes or induces or contributes to the infringement of the Ashley '564 patent, within the United States prior to the expiration of the aforementioned patent, including any later expiration of any patent term extension or exclusivity for the patents to which Plaintiffs are or will become entitled, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest; and

E. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

Jack B. Blumenfeld (#1014)
Jeremy A. Tigan (#5239)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
jtigan@mnat.com
Attorneys for Plaintiffs

OF COUNSEL:

Gerald J. Flattmann
Evan D. Diamond
Vanessa Y. Yen
KING & SPALDING LLP
1185 Avenue of the Americas
New York, NY 10036
(212) 556-2100
gflattmann@kslaw.com
ediamond@kslaw.com
vyen@kslaw.com

October 15, 2018
12293382